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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,449	08/03/2001	Frank-Roman Lauter	101215-68	1778
27387	7590	11/03/2003	EXAMINER	
BRUCE LONDA NORRIS, MCLAUGHLIN & MARCUS, P.A. 220 EAST 42ND STREET, 30TH FLOOR NEW YORK, NY 10017			HORLICK, KENNETH R	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/922,449	LAUTER ET AL.	
	Examiner	Art Unit	
	Kenneth R Horlick	1637	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21 and 24 is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☒ Claim(s) 15, 22 and 23 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08/03/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1 (3 pages)</u> | 6) <input type="checkbox"/> Other: _____ |

1. Claim 15 is objected to because of the following informality: "wherein that the" in line 1. Correction is required.

2. Claims 22 and 23 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 21 is drawn to a kit comprising certain reagents, but claims 22 and 23 further limit claim 21 insofar as how the kit is to be used. It is suggested that these claims be amended by indicating which reagent(s) in the kit are to be further limited.

3. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) These claims are confusing because they are drawn to methods, but it is not clear what steps are required in independent claim 1. Contributing to this confusion are: the language "characterized in that", for which the scope is unclear; the language "involving extracting" as it cannot be determined what is encompassed; and the fact that some recited steps are labeled as "a" and "b" while other apparent steps are not given such headers, i.e., the extraction and calculating steps. It is suggested that the claim be

amended to clarify which steps are required, with consistent terminology and conventional U.S. claim language such as "comprising the steps of".


B) Claims 19 and 20 are further confusing because of the language "preferably", which renders the scope unclear. Applicant may wish to consider the use of further dependent claims to cover the desired subject matter.

4. Claims 21 and 24 are allowable. Claims 22 and 23 are free of the prior art but are objected to, and claims 1-20 are free of the prior art, but are rejected for other reasons. These methods and kits require a first PCR reaction for amplifying a transgene and internal control transgene using primers P1 and P2, and fluorescence-labeled probes S1 and S2, as well as a second PCR reaction for amplifying a reference gene and internal control reference gene using primers P3 and P4, and fluorescence-labeled probes S2 and S3. Studer et al. teach quantitative PCR methods which involve amplification of a transgene and internal control transgene, but not a reference gene. While the use of various controls in amplification reactions was well known in the art, no prior art has been found teaching or suggesting carrying out two separate quantitative amplifications, one using a transgene and transgene internal control, and the other using a reference gene and reference internal control, including the use of the required probes and primers, such as the common probe S2. Sestini et al. and Yamashita et al. (US 2002/0100082) are made of record as references of interest.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Kenneth R Horlick
Primary Examiner
Art Unit 1637

10/29/03